

JS 44 (Rev. 12/07) (cand rev 1-16-08)

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON PAGE TWO OF THE FORM.)

## I. (a) PLAINTIFFS

KAREN BROWN, Individually and on Behalf of the Estate of RONALD T. BROWN, JR.,

## DEFENDANTS

See Attached List

(2)

(b) County of Residence of First Listed Plaintiff San Francisco (EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

~~MAC~~

ADR

Lawrence J. Gornick and Debra DeCarli 415-646-7160

Levin Simes Kaiser & Gornick

44 Montgomery Street, Suite 3600

San Francisco CA 94104

## II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

<input type="checkbox"/> 1 U.S. Government Plaintiff	<input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party)
<input type="checkbox"/> 2 U.S. Government Defendant	<input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

PTF	DEF	PTF	DEF
<input type="checkbox"/> 1 Citizen of This State	<input type="checkbox"/> 1 Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4
<input checked="" type="checkbox"/> 2 Citizen of Another State	<input type="checkbox"/> 2 Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5
<input type="checkbox"/> 3 Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3 Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

## IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance	<input type="checkbox"/> PERSONAL INJURY	<input type="checkbox"/> PERSONAL INJURY	<input type="checkbox"/> 422 Appeal 28 USC 158	<input type="checkbox"/> 400 State Reapportionment
<input type="checkbox"/> 120 Marine	<input type="checkbox"/> 310 Airplane	<input type="checkbox"/> 362 Personal Injury—Med. Malpractice	<input type="checkbox"/> 423 Withdrawal 28 USC 157	<input type="checkbox"/> 410 Antitrust
<input type="checkbox"/> 130 Miller Act	<input type="checkbox"/> 315 Airplane Product Liability	<input checked="" type="checkbox"/> 365 Personal Injury—Product Liability		<input type="checkbox"/> 430 Banks and Banking
<input type="checkbox"/> 140 Negotiable Instrument	<input type="checkbox"/> 320 Assault, Libel & Slander	<input type="checkbox"/> 368 Asbestos Personal Injury Product Liability		<input type="checkbox"/> 450 Commerce
<input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment	<input type="checkbox"/> 330 Federal Employers' Liability			<input type="checkbox"/> 460 Deportation
<input checked="" type="checkbox"/> 151 Medicare Act	<input type="checkbox"/> 340 Marine	<input type="checkbox"/> 370 Other Fraud		<input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations
<input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans)	<input type="checkbox"/> 345 Marine Product Liability	<input type="checkbox"/> 371 Truth in Lending		<input type="checkbox"/> 480 Consumer Credit
<input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits	<input type="checkbox"/> 350 Motor Vehicle	<input type="checkbox"/> 380 Other Personal Property Damage		<input type="checkbox"/> 490 Cable/Sat TV
<input type="checkbox"/> 160 Stockholders' Suits	<input type="checkbox"/> 355 Motor Vehicle Product Liability	<input type="checkbox"/> 385 Property Damage Product Liability		<input type="checkbox"/> 810 Selective Service
<input type="checkbox"/> 190 Other Contract	<input type="checkbox"/> 360 Other Personal Injury			<input type="checkbox"/> 850 Securities/Commodities/ Exchange
<input type="checkbox"/> 195 Contract Product Liability				<input type="checkbox"/> 875 Customer Challenge 12 USC 3410
<input type="checkbox"/> 196 Franchise				<input type="checkbox"/> 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	SOCIAL SECURITY	<input type="checkbox"/> 891 Agricultural Acts
<input type="checkbox"/> 210 Land Condemnation	<input type="checkbox"/> 441 Voting	<input type="checkbox"/> 510 Motions to Vacate Sentence	<input type="checkbox"/> 861 HIA (1395ff)	<input type="checkbox"/> 892 Economic Stabilization Act
<input type="checkbox"/> 220 Foreclosure	<input type="checkbox"/> 442 Employment	<input type="checkbox"/> Habeas Corpus:	<input type="checkbox"/> 862 Black Lung (923)	<input type="checkbox"/> 893 Environmental Matters
<input type="checkbox"/> 230 Rent Lease & Ejectment	<input type="checkbox"/> 443 Housing/ Accommodations	<input type="checkbox"/> 530 General	<input type="checkbox"/> 863 DIWC/DIWW (405(g))	<input type="checkbox"/> 894 Energy Allocation Act
<input type="checkbox"/> 240 Torts to Land	<input type="checkbox"/> 444 Welfare	<input type="checkbox"/> 535 Death Penalty	<input type="checkbox"/> 864 SSID Title XVI	<input type="checkbox"/> 895 Freedom of Information Act
<input type="checkbox"/> 245 Tort Product Liability	<input type="checkbox"/> 445 Amer. w/Disabilities - Employment	<input type="checkbox"/> 540 Mandamus & Other	<input type="checkbox"/> 865 RSI (405(g))	<input type="checkbox"/> 900 Appeal of Fee Determination
<input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 446 Amer. w/Disabilities - Other	<input type="checkbox"/> 550 Civil Rights		<input type="checkbox"/> Under Equal Access to Justice
	<input type="checkbox"/> 440 Other Civil Rights	<input type="checkbox"/> 555 Prison Condition	<input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 950 Constitutionality of State Statutes
IMMIGRATION				
		<input type="checkbox"/> 462 Naturalization Application		
		<input type="checkbox"/> 463 Habeas Corpus – Alien Detainee		
		<input type="checkbox"/> 465 Other Immigration Actions		

## V. ORIGIN (Place an "X" in One Box Only)

<input checked="" type="checkbox"/> 1 Original Proceeding	<input type="checkbox"/> 2 Removed from State Court	<input type="checkbox"/> 3 Remanded from Appellate Court	<input type="checkbox"/> 4 Reinstated or Reopened	<input type="checkbox"/> 5 another district (specify)	Transferred from	<input type="checkbox"/> 6 Multidistrict Litigation	Appeal to District
							<input type="checkbox"/> 7 Judge from Magistrate Judgment

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
28 USC 1332

Brief description of cause:

Product Liability

## VI. CAUSE OF ACTION

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND:  Yes  No

## VII. REQUESTED IN COMPLAINT: VIII. RELATED CASE(S) IF ANY

PLEASE REFER TO CIVIL L.R. 3-12 CONCERNING REQUIREMENT TO FILE "NOTICE OF RELATED CASE". MDL 1909 (pending)

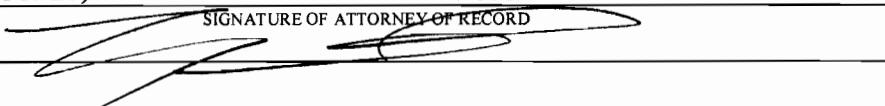
IX. DIVISIONAL ASSIGNMENT (CIVIL L.R. 3-2)  
(PLACE AND "X" IN ONE BOX ONLY)

SAN FRANCISCO/OAKLAND

SAN JOSE

DATE  
February 15, 2008

SIGNATURE OF ATTORNEY OF RECORD



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 2 Debra DeCarli (SBN 237642)  
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E-filing

6  
 7  
 8  
**UNITED STATES DISTRICT COURT**  
**NORTHERN DISTRICT OF CALIFORNIA**  
**SAN FRANCISCO DIVISION**

EDL

9  
 10  
 11 KAREN BROWN, Individually and on Behalf  
 of the Estate of RONALD T. BROWN, JR.,

Case No: **CV 08 0974**  
 ORIGINAL COMPLAINT

DEMAND FOR JURY TRIAL

12 Plaintiffs,  
 vs.  
 13  
 14 BAYER HEALTHCARE  
 PHARMACEUTICALS, INC.; BAYER  
 HEALTHCARE LLC; GENERAL ELECTRIC  
 COMPANY; GE HEALTHCARE, INC.;  
 15 TYCO INTERNATIONAL, INC.; COVIDIEN,  
 INC.; TYCO HEALTHCARE GROUP, LP;  
 16 MALLINCKRODT, INC.; and BRACCO  
 DIAGNOSTICS, INC.

17  
 18 Defendants.  
 19

20 Plaintiff Karen Brown, individually and on behalf of the estate of Ronald T. Brown, Jr.,  
 21 (hereinafter "Plaintiffs") alleges as follows:

22 **NATURE OF THE CASE**

23 1. Plaintiff Ronald T. Brown, Jr. ("Mr. Brown" or "Plaintiff") had nephrogenic systemic  
 24 fibrosis ("NSF"). NSF is an incurable, painful, and deadly disease. Mr. Brown contracted NSF as a  
 25 result of receiving intravenous injections of gadolinium-based contrast agents manufactured by the  
 26 Defendants. Gadolinium-based contrast agents are not safe for use in individuals such as Plaintiff who  
 27 have impaired kidney function. Defendants represented that the gadolinium-based contrast agents  
 28 were safe and failed to warn of the risks associated with gadolinium-based contrast agents.

## **JURISDICTION AND VENUE**

2. This Court has jurisdiction pursuant to 28 USC § 1332. Plaintiffs are citizens of a state that is different from the states where Defendants are incorporated and have their respective principal places of business. The amount in controversy for this case exceeds \$75,000. Venue pursuant to 28 USC § 1331 is proper because Defendants have sufficient contacts within the City and County of San Francisco, California to subject each of them to personal jurisdiction.

## INTRADISTRICT ASSIGNMENT

3. On information and belief, a substantial part of the events or omissions which give rise to the claim occurred in the County and City of San Francisco.

## PARTIES

***Plaintiffs***

4. Ronald T. Brown, Jr. was a resident of the state of Pennsylvania until his death. Karen Brown, the widow of Ronald Brown, is a resident of the state of Pennsylvania.

### *Defendants*

5. Defendants Bayer HealthCare Pharmaceuticals, Inc. and Bayer Healthcare LLC (jointly referred to as “Bayer”) manufacture, market, and sell Magnevist, a gadolinium-based contrast agent that, on information and belief, was injected into Plaintiff.

6. Defendant Bayer HealthCare LLC is a Delaware business entity with its principal place of business in New York.

7. Defendant Bayer HealthCare Pharmaceuticals, Inc. is a Delaware business entity with its principal place of business in New Jersey. Defendant Bayer HealthCare Pharmaceuticals, Inc. is the U.S.-based pharmaceuticals unit of Bayer Healthcare LLC.

8. At all times relevant to this complaint, Bayer was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing Magnevist into interstate commerce.

9. Defendants General Electric Company and GE Healthcare, Inc. (jointly referred to as "GE") manufacture, market, and sell Omniscan, a gadolinium-based contrast agent that, on information and belief, was injected into Plaintiff.

1       10.   Defendant General Electric Company is a New York business entity with its principal  
2 place of business in Connecticut.

3       11.   Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of  
4 business in New Jersey.

5       12.   At all times relevant to this complaint, GE was in the business of designing, licensing,  
6 manufacturing, distributing, selling, marketing, promoting, and introducing Omniscan into interstate  
7 commerce.

8       13.   Defendants Tyco International Inc., Covidien Inc., Tyco Healthcare Group LP, and  
9 Mallinckrodt, Inc. (collectively referred to as "Tyco") manufacture, market, and sell OptiMARK, a  
10 gadolinium-based contrast agent that, on information and belief, was injected into Plaintiff.

11       14.   Defendant Tyco International Inc. is a Massachusetts corporation with its principal  
12 place of business in New Jersey.

13       15.   Defendant Covidien Inc. is a Delaware corporation with its principal place of business  
14 in New Hampshire. Tyco Healthcare Group LP was a Delaware corporation with its principal place of  
15 business in Massachusetts. Tyco Healthcare LP was a subsidiary of Tyco International until  
16 approximately July 2007, when Tyco Healthcare LP became Covidien Inc. and separated from Tyco  
17 International.

18       16.   Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of  
19 business in Missouri. Mallinckrodt was a business unit of Tyco Healthcare LP and is currently a  
20 business unit of Covidien Inc.

21       17.   At all times relevant to this complaint, Tyco was in the business of designing, licensing,  
22 manufacturing, distributing, selling, marketing, promoting, and introducing OptiMARK into interstate  
23 commerce.

24       18.   Defendant Bracco Diagnostics, Inc. ("Bracco") manufactures, markets, and sells  
25 MultiHance and ProHance, gadolinium-based contrast agents that, on information and belief, were  
26 injected into Plaintiff.

27       19.   Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business  
28 in New Jersey.

20. At all times relevant to this complaint, Bracco was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing MultiHance and ProHance into interstate commerce.

21. The Bayer, GE, Tyco, and Bracco Defendants are collectively referred to as Defendants.

## FACTS

22. Mr. Brown was diagnosed with NSF in or around January of 2005.

23. NSF is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin after receiving a gadolinium-based contrast agent injection. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement. NSF also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver, and musculature, and that can inhibit their ability to function properly and may lead to death. NSF is a progressive disease for which there is no known cure.

24. NSF is a man-made disease. It only occurs in patients who have received a gadolinium-based contrast agent.

25. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human body. The only known route for gadolinium to enter the human body is injection of a gadolinium-based contrast agent.

26. Because gadolinium is toxic, it has to be coated to keep it from coming in contact with human tissue when injected. This coating process is called chelation.

27. Gadolinium is eliminated from the body by the kidneys. Gadolinium-based contrast agents are not safe if the chelate separates from the gadolinium, which is what happens over time if kidneys are not functioning properly. Individuals with impaired kidney function risk dechelation and cannot efficiently or quickly eliminate gadolinium from their bodies. Defendants never tested the safety of their gadolinium-based contrast agents in individuals with kidney impairment.

1       28. On information and belief, the gadolinium-based contrast agents injected into Plaintiff  
2 were manufactured by Defendants.

3       29. In pre-clinical studies during which gadolinium-based contrast agents were injected into  
4 laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the  
5 kidneys and other body organs occurred.

6       30. During the years that Defendants have manufactured, marketed, distributed, sold, and  
7 administered gadolinium-based contrast agents, there have been numerous case reports, studies,  
8 assessments, papers, and other clinical data that have described and/or demonstrated NSF in  
9 connection with the use of gadolinium-based contrast agents.

10      31. Plaintiff received MRIs and/or MRAs utilizing gadolinium-based contrast agents.

11      32. Plaintiff had impaired kidney function at the time he received his first injection of  
12 gadolinium-based contrast agent and continued to have impaired kidney function at the time he  
13 received each subsequent injection of gadolinium-based contrast agent.

14      33. During the time period when Plaintiff received injections of Defendants' gadolinium-  
15 based contrast agents, Defendants knew or should have known that the use of gadolinium-based  
16 contrast agents created a risk of serious bodily injury and death in patients with impaired kidney  
17 function.

18      34. Defendants failed to warn Plaintiff and his healthcare providers about the serious health  
19 risks associated with gadolinium-based contrast agents, and failed to disclose the fact that there were  
20 safer alternatives.

21      35. As a direct and proximate result of receiving injections of gadolinium-based contrast  
22 agents manufactured, marketed, distributed, and sold by Defendants, Plaintiff developed NSF.

23      36. Defendants have repeatedly and consistently failed to advise consumers and/or their  
24 healthcare providers of the causal relationship between gadolinium-based contrast agents and NSF in  
25 patients with kidney impairment. Defendants knew or should have known of the risk of NSF posed by  
26 gadolinium-based contrast agents to individuals with impaired kidney function years before they  
27 finally issued warnings.

28      37. It was not until September 2007 that Bayer, GE, Bracco, and Mallinckrodt finally sent

1 letters to healthcare providers warning them of the risk of NSF to kidney impaired individuals who  
2 received MRIs using gadolinium-based contrast agents.

3 38. Had Plaintiff and/or his healthcare providers been warned about the risks associated  
4 with gadolinium-based contrast agents, he would not have been administered gadolinium-based  
5 contrast agents and would not have been afflicted with NSF.

6 39. As a direct and proximate result of Plaintiff being administered gadolinium-based  
7 contrast agents, Plaintiff suffered severe physical injury and pain and suffering, including, but not  
8 limited to, the effects of NSF.

9 40. As a direct and proximate result of being administered gadolinium-based contrast  
10 agents, Plaintiff suffered significant mental anguish and emotional distress and Plaintiffs will continue  
11 to suffer significant mental anguish and emotional distress in the future.

12 41. As a direct and proximate result of being administered gadolinium-based contrast  
13 agents, Plaintiffs have also incurred medical expenses and other economic damages.

14 **DISCOVERY RULE & FRAUDULENT CONCEALMENT**

15 42. The discovery rule should be applied to toll the running of the statute of limitations  
16 until Plaintiffs knew or through the exercise of reasonable care and diligence should have known of  
17 the existence of their claims against all Defendants. The nature of Plaintiffs' injuries and damages,  
18 and their relationship to gadolinium-based contrast agents used in conjunction with MRIs and MRAs,  
19 was not discovered, and through reasonable care and due diligence could not have been discovered, by  
20 Plaintiffs, until a time less than two years before the filing of this Complaint. Therefore, under  
21 appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable  
22 statutory limitations period.

23 43. Defendants are estopped from asserting a statute of limitations defense because all  
24 Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injury and the connection  
25 between the injury and all Defendants' tortious conduct.

26 **FIRST CAUSE OF ACTION**

27 **STRICT LIABILITY: FAILURE TO WARN**

28 44. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

45. Defendants' gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents, were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or should have known that their products created significant risks of serious bodily harm and death to consumers. Defendants failed to adequately warn consumers and their healthcare providers of such risks.

46. Because of Defendants' failure to provide adequate warnings with their products, Plaintiff was injected with gadolinium-based contrast agents which the Defendants manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce. Those gadolinium-based contrast agents are the legal cause of Plaintiff's physical injuries, harm, damages, and economic loss.

## **SECOND CAUSE OF ACTION**

## **STRICT LIABILITY: DESIGN DEFECT**

47. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

48. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.

49. The gadolinium-based contrast agents manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of the products exceeded the benefits associated with their design or formulation, or were more dangerous than an ordinary consumer would expect.

50. The foreseeable risks associated with the design or formulation of gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents, include, but are not limited to, the fact that the design or formulation of gadolinium-based contrast agents are more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

51. As a direct and proximate result of Plaintiff being administered gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced into the stream of commerce by Defendants, Plaintiff suffered physical injury, harm, damages, and economic loss.

### **THIRD CAUSE OF ACTION**

## **STRICT LIABILITY: FAILURE TO ADEQUATELY TEST**

52. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

53. Defendants advised consumers and the medical community that gadolinium-based contrast agents were safe for use. Defendants failed to adequately test gadolinium-based contrast agents with respect to their use by consumers with kidney impairment.

54. Had Defendants adequately tested the safety of gadolinium-based contrast agents for use by consumers with kidney impairment and disclosed those results to the medical community or the public, Plaintiff would not have been administered gadolinium-based contrast agents.

55. As a direct and proximate result of Defendants' failure to adequately test the safety of gadolinium-based contrast agents and as a direct and proximate result of Plaintiff being administered gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced into the stream of commerce by Defendants, Plaintiff suffered physical injury, harm, damages, and economic loss.

## **FOURTH CAUSE OF ACTION**

## **NEGLIGENCE**

56. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

57. Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events.

58. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents in that they knew

1 or should have known that the products could cause significant bodily harm or death and were not safe  
 2 for use by certain types of consumers.

3 59. Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast  
 4 agents and the labeling of MRI and MRA machines designed to be used in conjunction with  
 5 gadolinium-based contrast agents and failed to issue to consumers and their health care providers  
 6 adequate warnings concerning the risks of serious bodily injury or death due to the use of gadolinium-  
 7 based contrast agents and the MRI and MRA machines designed to be used in conjunction with  
 8 gadolinium-based contrast agents.

9 60. Despite the fact that Defendants knew or should have known that gadolinium-based  
 10 contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-  
 11 based contrast agents posed a serious risk of bodily harm to consumers, Defendants unreasonably  
 12 continued to manufacture and market gadolinium-based contrast agents and the MRI and MRA  
 13 machines designed to be used in conjunction with gadolinium-based contrast agents for administration  
 14 to MRI and MRA patients with kidney impairment and failed to exercise reasonable care with respect  
 15 to post-sale warnings and instructions for safe use.

16 61. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff  
 17 would suffer injury as a result of their failure to exercise ordinary care as described above.

18 62. As a direct and proximate result of Defendants' negligence, Plaintiff suffered physical  
 19 injuries, harm, damages, and economic loss.

20 63. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful,  
 21 malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the  
 22 health, safety, and rights of Plaintiffs and other users of Defendants' products, and for the primary  
 23 purpose of increasing Defendants' profits. As such, Plaintiffs are entitled to exemplary damages.

#### **FIFTH CAUSE OF ACTION**

#### **NEGLIGENT MISREPRESENTATION**

26 64. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

27 65. Defendants supplied the public and Plaintiff's healthcare providers with materially false  
 28 and incomplete information with respect to the safety of their gadolinium-based contrast agents.

66. The false information supplied by Defendants was that gadolinium-based contrast agents were safe.

67. In supplying this false information, Defendants failed to exercise reasonable care.

68. The false information communicated by Defendants to Plaintiff and his healthcare providers was material and Plaintiff justifiably relied in good faith on the information to his detriment.

69. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was administered gadolinium-based contrast agents and suffered physical injury, harm, damages, and economic loss.

## **SIXTH CAUSE OF ACTION**

## **FRAUD**

70. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

71. Defendants knowingly and intentionally made materially false and misleading representations to Plaintiff's healthcare providers and to the public, to the effect that gadolinium-based contrast agents were safe for use and that their labeling, marketing, and promotional materials fully described all known risks associated with their product.

72. Defendants' representations were in fact false. Gadolinium-based contrast agents are not safe for use and Defendants' labeling, marketing, and promotional materials did not fully describe all known risks of the products.

73. Defendants had actual knowledge that gadolinium-based contrast agents created an unreasonable risk of serious bodily injury and death to consumers, especially patients with kidney impairment.

74. Defendants knowingly and intentionally omitted this information from their labeling, marketing, and promotional materials and instead, labeled, promoted, and marketed their products as safe for use in order to increase and sustain sales.

75. When Defendants made representations that gadolinium-based contrast agents were safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, his physicians, and the public, the fact that their gadolinium-based contrast agents are not safe for use in consumers with kidney impairment.

76. Defendants had a duty to disclose that gadolinium-based contrast agents are not safe for use in patients with kidney impairment. Defendants had superior knowledge of these facts that were material to Plaintiff and his physicians' decisions to use gadolinium-based contrast agents.

77. Plaintiff and his healthcare providers reasonably and justifiably relied on the Defendants' representations that gadolinium-based contrast agents were safe for human use and that Defendants' labeling, marketing, and promotional materials fully described all known risks associated with the products.

78. Plaintiff did not know, and could not have learned of the facts that the Defendants omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had Plaintiff and his healthcare providers known that gadolinium-based contrast agents are not safe for use in patients with renal insufficiency, Plaintiff would not have been injected with gadolinium-based contrast agents.

79. As a direct and proximate result of Defendants' misrepresentations and concealment, Plaintiff was administered gadolinium-based contrast agents and suffered physical injury, harm, damages, and economic loss.

80. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

## **SEVENTH CAUSE OF ACTION**

## **FRAUD: CONCEALMENT, SUPPRESSION OR**

## **OMISSION OF MATERIAL FACTS**

81. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

82. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risk associated with the use of their gadolinium-based contrast agents, including but not limited to the risks to patients with kidney impairment of developing NSF, and the fact that safer alternatives were available. Further, Defendants purposely downplayed and understated the serious nature of the risks associated with use of their gadolinium-based contrast agents in order to increase and sustain sales.

83. As a direct and proximate result of Defendants' concealment of material facts, Plaintiff was administered gadolinium-based contrast agents and suffered physical injury, harm, damages, and economic loss.

84. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

## **EIGHTH CAUSE OF ACTION**

## **BREACH OF EXPRESS WARRANTY**

85. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

86. Defendants expressly warranted that gadolinium-based contrast agents were safe and effective.

87. The gadolinium-based contrast agents manufactured and sold by Defendants did not conform to these express representations because they cause serious injury to consumers when administered in recommended dosages.

88. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered physical injury, harm, damages, and economic loss.

## **NINTH CAUSE OF ACTION**

## **BREACH OF IMPLIED WARRANTY**

89. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

90. At the time Defendants designed, manufactured, marketed, sold, and distributed gadolinium-based contrast agents, Defendants knew of the use for which gadolinium-based contrast agents was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

91. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether gadolinium-based contrast agents were of merchantable quality and safe for their intended use and upon Defendants' implied warranty as to such matters.

92. Contrary to such implied warranty, gadolinium-based contrast agents were not of merchantable quality or safe for their intended use because the product was unreasonably dangerous as described above.

93. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered physical injury, harm, damages and economic loss.

## **TENTH CAUSE OF ACTION**

## **VIOLATION OF PENNSYLVANIA**

## UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW (“UTPCPL”)

94. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

95. Defendants' acts and business practices constitute unlawful methods of competition and unfair or deceptive acts within the meaning of 73 P.S. 201-1 et. seq., the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL") in violation of 73 P.S. 201-2(4)(ii), (iii), (v), (vii), (ix), (xiv), and (xxi) including but not limited to the following:

a. Marketing, promoting or selling Magnevist, Omniscan OptiMARK, MultiHance, or ProHance for use with MRAs and other off-label uses by impliedly representing that such products are approved for use with MRAs and other off-label uses, when in fact there is no such approval;

b. Representing that gadolinium-based contrast agents are safe and effective for all patients, including patients with kidney impairment, when in fact they are not;

c. Representing that MRIs and MRAs using gadolinium-based contrast agents are safer or more effective than other imaging methods that do not require the use of gadolinium-based contrast agents when in fact they are not:

d. Marketing, promoting or selling their products as safer or superior to other brands of gadolinium-based contrast agents:

e. Marketing, promoting or selling Magnevist, Omniscan, OptiMARK, MultiHance or ProHance as inert or with words to that effect:

f. Marketing, promoting or selling Magnevist, Omniscan OptiMARK, MultiHance or ProHance for use with MRAs or other off-label uses by expressly or impliedly representing that they are safe for such use; and

1 g. Remaining silent despite their knowledge of the growing body of evidence regarding  
 2 the danger of NSF and doing so because the prospect of huge profits outweighed health and safety  
 3 issues.

4 96. As a direct and proximate result of Defendants' unfair methods of competition and  
 5 unfair or deceptive actions or practices, Plaintiff was administered gadolinium-based contrast agents  
 6 and has suffered serious physician injury, harm, damages, and economic loss and will continue to  
 7 suffer such harm, damages, and economic loss in the future.

8 **ELEVENTH CAUSE OF ACTION**

9 **LOSS OF CONSORTIUM**

10 97. Plaintiff Karen Brown, individually and on behalf of the Estate of Ronald T. Brown, Jr.,  
 11 incorporates by reference and realleges each paragraph set forth above.

12 98. This cause of action is brought on behalf of all persons entitled by statute to assert these  
 13 claims. By reason of the injuries suffered by Ronald T. Brown, Jr. and Plaintiffs, Karen Brown,  
 14 individually, and on behalf of the Estate of Ronald T. Brown, Jr., suffered and seek damages as  
 15 permitted by Pennsylvania's survival statutes for the following losses: (1) loss of support from the Mr.  
 16 Brown's reasonably expected earnings, (2) loss of Mr. Brown's services, (3) loss of Mr. Brown's  
 17 companionship, including care, assistance, attention, protection, advice, guidance, counsel, instruction,  
 18 training, and education, (4) loss of prospective inheritance; (5) sorrow, mental anguish, and pain and  
 19 suffering; and all other damages allowed by the laws of their respective states.

20 **ELEVENTH CAUSE OF ACTION**

21 **SURVIVAL ACTION**

22 99. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

23 100. Ronald T. Brown, Jr., had he lived, would have had causes of action against Defendants  
 24 as alleged above.

25 101. As a proximate result of the conduct of Defendants as described above, Ronald T.  
 26 Brown, Jr. suffered personal injuries, pain, suffering, and other damages.

27 102. Pursuant to the Pennsylvania Survival Act, Defendants are liable for damages to Karen  
 28 Brown, individually and on behalf of the Estate of Ronald T. Brown, Jr.

1                   **WHEREFORE, Plaintiffs pray for relief as follows:**

2                   1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to  
3                   pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, and other  
4                   non-economic damages in an amount to be determined at trial of this action;

5                   2. Past and future medical expenses, income, and other economic damages in an amount to be  
6                   determined at trial of this action;

7                   3. Punitive damages in an amount to be determined at trial of this action;

8                   4. Pre- and post-judgment interest;

9                   5. Attorneys' fees, expenses, and costs; and

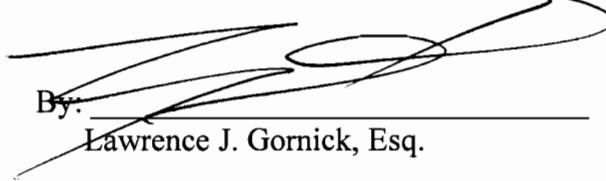
10                  6. Such further relief as this Court deems necessary, just, and proper.

11                  **DEMAND FOR JURY TRIAL**

12                  Plaintiffs hereby demand a trial by jury.

13                  Respectfully submitted this 15<sup>th</sup> day of February, 2008.

14                  LEVIN SIMES KAISER & GORNICK LLP

15                    
16                  By: \_\_\_\_\_  
17                  Lawrence J. Gornick, Esq.